

### **REMARKS**

The present application is directed to compositions comprising a combination of electroprocessed materials and substances, and methods of making and using the same. Claims 1, 6, 9 and 24-36 are currently pending in this application. Claims 2-5, 7-8, 10-23 are cancelled without prejudice. Claims 1, 24-26, 28 and 29 are currently amended. Claim 36 is new. Amendments herein do not introduce any new matter and support for the amendments and new claims are found throughout the specification. Favorable consideration of the currently pending claims is respectfully requested in light of the following remarks.

#### ***Claim rejections under 35 U.S.C. §102(b)***

##### **Coffee et al.**

In the Final Office Action mailed July 6, 2006, the Examiner rejected Claims 1, 6 and 24-32 under 35 U.S.C. §102(b) as being anticipated by Coffee *et al.*, (WO 98/03267 see equivalent U.S. 6,252,129, hereinafter Coffee). The Examiner states Coffee fails to disclose a composition of electroprocessed materials comprising one specific natural material and two synthetic materials.

Applicants respectfully submit that the amendments to the Claims overcome the rejection. Applicants respectfully submit Coffee fails to teach or suggest an electroprocessed composition as recited in amended Claim 1.

Claim 1 is amended to clarify that the composition comprises an electroprocessed material and a substance, **wherein the electroprocessed material** comprises at least **one natural material and two synthetic materials** (polymers).

Applicants respectfully submit Coffee fails to teach or suggest a fibril, mat or gel prepared from an electroprocessed material comprising **two or more synthetic polymers** and at least one **natural material** selected from the Markush group of Claim 1. Applicants submit Coffee discloses a **polymer**, such as PVA alone, or polyhydroxybutyric acid alone, to form an electroprocessed fibril or fiber (see column 9, last paragraph of U.S. Patent 6,252,129 and column 10, first full paragraph). Accordingly, Applicants respectfully submit

Coffee fails to teach or suggest an **electroprocessed material** comprising a **natural material** and at least **two polymers**.

Additionally, Applicants submit Coffee fails to teach or suggest a composition comprising a substance (such as a therapeutic or cosmetic substance) and an electroprocessed material (comprising two or more polymers and at least one natural material selected from the Markush group of Claim 1).

Regarding Claim 25, the **electroprocessed material** comprises a combination of **one or more natural materials** and **two or more polymers**. Applicants concur with the Examiner (as stated on page 9 of the Office Action dated July 26, 2005), and respectfully submit Coffee fails to teach or suggest an electroprocessed composition comprising a combination of one or more natural materials and two or more polymers.

Regarding Claim 28, Applicants respectfully submit Coffee fails to teach or suggest an electroprocessed composition comprising electroprocessed collagen fibers comprising a repeated banding pattern, **wherein the repeated banding pattern occurs at a spacing of about 65 nm to 67 nm**.

Accordingly, Applicants respectfully assert they have overcome the rejection and request its withdrawal.

Martin et al.

In the Final Office Action mailed July 6, 2006, the Examiner rejected Claims 1, 6, 9, 24-26 and 30-32 under 35 U.S.C. §102(b) as being anticipated by Martin *et al.*, (U.S. 4,043,331, hereinafter Martin). The Examiner states Martin discloses making a fibrillar mat. The Examiner states various polymers may be used to form the fibers. The Examiner concludes various **immiscible substances** such as biological components can be incorporated within the mat. The Examiner concludes Martin discloses crosslinking of water soluble polymers.

However, Martin fails to teach or suggest an **electroprocessed material** comprising **two or more synthetic polymers** and **at least one natural material** selected from the Markush group of Claim 1. For example, Martin fails to teach or suggest

electroprocessing of two or more synthetic polymers **and** an amino acid, or two or more synthetic polymers **and** a protein. Specifically, Martin fails to teach or suggest that a **natural material can be electroprocessed**.

Furthermore, Applicants wish to clarify that Martin teaches that immiscible substances such as biological components may be added to the mat or between layers of the mat **after formation of the electroprocessed fibers** (see column 2, lines 35-45). In contrast, the claimed invention requires two or more synthetic polymers and at least one natural material are **electroprocessed simultaneously to form the electroprocessed material** (see Examples 1 and 2 of the instant specification). The electroprocessed material is combined with a “substance” to form the composition of Claim 1. Applicants respectfully submit the “substance” as recited in Claim 1 may be equivalent to Martin’s “biological component”. Clearly, Martin fails to teach or suggest the claimed electroprocessed material (comprising two or more synthetic polymers and at least one natural material) and cannot therefore anticipate the composition recited in Claim 1.

Applicants respectfully submit that, as stated by the Examiner, the biological component of Martin is an “**immiscible substance**” and is therefore, **by definition**, not capable of mixing with a polymeric solution to form a combined electroprocessed material. In contrast, the **electroprocessed material** (i.e. electroprocessed fibers) of the instant invention comprise **both a natural material** (for example, a protein, such as collagen) **and two or more synthetic polymers**. Clearly, the electroprocessed material of the claimed invention is different to the electroprocessed material of Martin. Specifically, the claimed electroprocessed material requires both a natural and synthetic material. Martin teaches that only a synthetic material is electroprocessed.

Applicants respectfully assert Martin fails to teach or suggest the claimed invention. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102(b).

Doshi et al.

In the Final Office Action mailed July 6, 2006, the Examiner rejected Claims 1, 6 and 24-32 under 35 U.S.C. §102(b) as being anticipated by Doshi *et al.*, (“electrospinning process and applications of electrospun fibers”, J. Electrostatics 35:151-160, 1995, hereinafter Doshi). The Examiner states Doshi discloses making three dimensional compositions of electrospun fibers from solutions of water-soluble polymers, biopolymer and liquid crystalline polymers. The Examiner states **immiscible substances** such as an insecticide, a wound treating composition or blood may be incorporated into the composition. The Examiner also concludes **composite materials** may be produced **when the spinning solutions are changed successively** so that layers of different **polymers** are deposited on top of each other.

Applicants respectfully assert that the amendments to the Claims overcome the rejection. Applicants respectfully submit Doshi fails to teach or suggest an **electroprocessed material** comprising **two or more synthetic polymers and at least one natural material selected from the Markush group** of Claim 1. Specifically, Doshi fails to teach or suggest that a natural material can be electroprocessed. Doshi only teaches that a polyethylene oxide (PEO) solution (**one synthetic polymer**) can be electroprocessed (see page 153, first paragraph). As discussed above, the instant specification (see Examples 1 and 2) teaches that a **natural material and two or more synthetic polymers** can be electroprocessed simultaneously to form the electroprocessed material.

Applicants wish to clarify that Doshi teaches immiscible substances maybe added to the fibers or between layers of fibers to form a composite material **after formation of electroprocessed fibers** (see page 159, first paragraph). In contrast, the claimed invention requires two or more synthetic polymers and at least one natural material are **electroprocessed simultaneously to form the electroprocessed material** (see Examples 1 and 2 of the instant specification). The electroprocessed material of the instant application is combined with a “substance” to form the composition of Claim 1. Applicants respectfully submit the “substance” as recited in Claim 1 may be equivalent to Doshi’s “immiscible

substance". Clearly, Doshi fails to teach or suggest the claimed electroprocessed material (two or more synthetic polymers and at least one natural material) and cannot therefore anticipate the composition recited in Claim 1.

Applicants respectfully submit that an **"immsicble substance"**, by definition, is not capable of mixing with a polymeric solution to form a combined electroprocessed material. In contrast, the **electroprocessed material** (i.e. electroprocessed fibers) of the instant invention comprise **both a natural material** (for example, a protein, such as collagen) **and two or more synthetic polymers**. Clearly, the electroprocessed material of the claimed invention is different to the electroprocessed material of Doshi. Specifically, the claimed electroprocessed material requires both a natural and synthetic material. Doshi teaches that only a synthetic material is electroprocessed.

Applicants respectfully assert Doshi fails to teach each element of the claims and cannot therefore anticipate the claimed invention. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102(b).

***Claim rejections under 35 U.S.C. §102(e)***

In the Final Office Action mailed July 6, 2006, the Examiner rejected Claims 1, 6 and 24-32 under 35 U.S.C. §102(e) as being anticipated by Murphy *et al.*, (U.S. US 2002/0172705, hereinafter Murphy) as evidenced by Koseki et al., (US 5,922,356, hereinafter Koseki).

Applicants respectfully submit that the amendments to the Claims overcome the rejection. Murphy fails to teach or suggest an electroprocessed material comprising **two or more synthetic polymers and at least one natural material** as recited in Claim 1. As discussed above, the instant specification teaches that **a natural material and two or more synthetic polymers** are electroprocessed simultaneously to form an electroprocessed material (see Examples 1 and 2 of the instant application).

In contrast, Murphy discloses that induction of fibroblasts (cells) by electrostatic charge produces an extracellular matrix. Murphy fails to teach or suggest a

combination of **two synthetic polymers and one natural material** to form an electroprocessed material. Clearly, Murphy fails to teach or suggest the claimed electroprocessed material (two or more synthetic polymers and at least one natural material) and cannot therefore anticipate the composition recited in Claim 1.

Additionally, the deficiencies of Murphy are not satisfied by Koseki because Koseki fails to teach or suggest electroprocessing. Consequently, Koseki is silent with regard to electroprocessing of one or more natural materials and two or more synthetic materials as claimed herein. Accordingly, Koseki fails to teach or suggest an electroprocessing material comprising one or more natural materials and two or more synthetic polymers as claimed.

Applicants respectfully submit Murphy, alone, or in combination with Koseki fail to teach, suggest or motivate one of ordinary skill in the art to make the claimed invention. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102(e).

***Claim rejections under 35 U.S.C. §103(a)***

In the Final Office Action mailed July 6, 2006, the Examiner rejected Claims 1, 6, 9 and 24-32 under 35 U.S.C. §103(a) as being unpatentable over Coffee, Martin, Doshi, and Murphy, (already of record) in view of Mechanic (US 5,332,475). The Examiner stated Coffee, Martin, Doshi, and Murphy fail to explicitly disclose an electroprocessed composition comprising three specified electroprocessed polymers, one of which is natural material and two of which are synthetic.

The Examiner concluded it would be obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of the references to produce an electroprocessed material comprising one natural material and two synthetic materials. Specifically, the Examiner states Martin and Murphy teach that each material in the composition is selected because of its desired biological, physical or chemical properties.

Applicants respectfully assert that the amendments to the Claims overcome the rejection. The remarks provided above under Claim rejections under 35 U.S.C. §102(b) and 102(e) are repeated here.

Applicants respectfully submit that as discussed above, the **electroprocessed material** of the instant claims requires at least **one natural material and two or more synthetic materials** simultaneously electroprocessed to form the electroprocessed material. This is a distinct and separate composition to the teachings of the prior art. As discussed in Martin and Doshi, only one synthetic polymeric solution was electroprocessed. Therefore, there is **no motivation or suggestion to combine more than one synthetic polymer**. Additionally, immiscible materials were added to the composition after the formation of the electroprocessed fibers and are not therefore, part of the electroprocessed material per se.

In contrast, the **electroprocessed material** of the instant invention comprises **both** a natural material **and** two or more synthetic polymers **to form the electroprocessed material**. Applicants respectfully submit that there is no motivation or suggestion in the prior art to combine a natural material and two or more synthetic materials simultaneously to form an electroprocessed material.

Applicants respectfully submit one of ordinary skill in the art based on the teachings of Doshi and Martin **would not be motivated** to combine an **immiscible substance** (as taught by Doshi and Martin) with a **polymer solution** (as taught by Doshi and Martin) as suggested by the Examiner, because the individual components are **immiscible**. Accordingly, one of ordinary skill in the art can conclude based on the teachings of Doshi and Martin, that Doshi and Martin **teach away** from combining an immiscible substance and a polymeric solution to form an electroprocessed material because such a combination is not likely to result in a successful outcome.

Martin and Doshi fail to teach or suggest electroprocessing of a **natural material**. Consequently, Martin and Doshi fail to motivate or suggest electroprocessing of a **natural material**, such as a protein, **as an electroprocessed material per se**. In fact, Applicants respectfully assert that Martin and Doshi teach that electroprocessed fibers

consist **only of a synthetic polymer**. In contrast, Examples 1 and 2 of the instant application disclose combining **PGA, PLA and collagen** in solution and simultaneously electroprocessing the solution to form an electroprocessed material. Hence, the **electroprocessed material comprises PLA, PGA and collagen** (two synthetic polymers and one natural material).

Furthermore, Coffee fails to teach or suggest an electroprocessed material comprising two polymers and one natural material. Applicants submit that if one of ordinary skill in the art were to combine Coffee with Doshi and Martin, the **electroprocessed material** would not comprise two or more synthetic materials and one or more natural materials. Applicants submit there is no teaching or suggestion in the cited references alone, or in combination, that such a combination of elements would result in an effective composition. It is to the Applicants' credit that the composition, as claimed, is demonstrated to be effective and useful, as disclosed in the Examples and Figures of the instant application.

Applicants submit Mechanic fails to satisfy the deficiencies of Coffee, Doshi and Martin because Mechanic discloses crosslinking of proteins by chemical or irradiation means, which is not an element of the independent claims.

Accordingly, Applicants assert they have overcome the rejection under 35 U.S.C. §103(a) and request its withdrawal.

***Double Patenting-Obviousness type***

In the Final Office Action mailed July 6, 2006, the Examiner provisionally rejected Claims 1, 6, 9 and 24-32 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-3 and 18-42 of copending application 10/447,670. The Examiner stated the claims are not patentably distinct because the instant claims recite a genus of compositions, while the copending application recites electrospun collagen fibers.



Applicants respectfully submit that the amendments to the Claims overcome the rejection. Applicants respectfully submit the independent claims, as amended, represent patentably distinct inventions over the co-pending application 10/447,670. Accordingly, Applicants do not wish to file a terminal disclaimer at this time. Applicants respectfully request withdrawal of the rejection under the judicially created doctrine of obviousness-type double patenting.

### CONCLUSION

Based upon the amendments and remarks provided above, Applicants believe the pending Claims are in condition for allowance. A Notice of Allowance is therefore respectfully solicited.

No additional fees are believed due; however, the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment, to Deposit Account No. 11-0855.

If the Examiner believes any informalities remain in the application that may be corrected by Examiner's Amendment, or there are any other issues that can be resolved by telephone interview, a telephone call to the undersigned agent at (404) 815-6500 is respectfully solicited.

Respectfully submitted,



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